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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,969	03/21/2000	Jan Geliebter	96700/596	6902

7590                    08/13/2003

Craig J Arnold Esq  
Amster Rothstein & Ebenstein  
90 Park Avenue  
New York, NY 10016

[REDACTED] EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
1632	18

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/531,969	GELIEBTER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication; even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 May 2003.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 50-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 50-54, 58 and 59 is/are rejected.
- 7) Claim(s) 55-57 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 3/21/00 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>19</u> . | 6) <input type="checkbox"/> Other: _____                                    |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/20/03 has been entered.

Claims 1, 9 and 37-49 have been cancelled. New claims 50-59 have been added.

***Drawings***

The drawings filed on 3/21/00 have been approved.

***Sequence Compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicants are required to comply with all of the requirements of 37 C.F.R. §§ 1.821 through 1.825. Any response to this Office Action, which fails to meet all of these

requirements, will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. §§ 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

To avoid damage to a CRF by irradiation, a reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio  
(<http://www.uspto.gov/ebc/efs/downloads/documents.htm>), EFS Submission User Manual - ePAVE)
2. Mailed to: **U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202**
3. Mailed by Federal Express, United Parcel Service or other delivery service to: **U. S. Patent and Trademark Office, 2011 South Clark Place, Customer Window, Box Sequence, Crystal Plaza Two, Lobby, Room 1B03, Arlington, Virginia 22202**
4. Hand Carried directly to the Customer Window at: **2011 South Clark Place, Crystal Plaza Two, Lobby, Room 1B03, Box Sequence, Arlington, Virginia 22202**

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-54 and 58-59 as newly added are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. The previous rejection is maintained as it pertains to the newly added claims for the reasons of record advanced on pages 2-4 of the Office action mailed on 7/29/02.

Applicant's arguments filed on 5/20/03 have been fully considered but are not found persuasive. Applicants have provided the Christ declaration in support of the newly added claims.

The declaration under 37 CFR 1.132 filed 5/20/03 is insufficient to overcome the rejection of claims 50-54 and 58-59 based upon 35 U.S.C 112, 1<sup>st</sup> paragraph, as set forth in the last Office action because: The instant specification discusses that "despite the plethora of known K+ channel subtypes, experimental and clinical data in human corporal smooth muscle provide evidence for the presence and physiological relevance of only two: (1) the metabolically-gated K+ channel (i.e., K<sub>ATP</sub>), and (2) the large-conductance, calcium-sensitive K+ channel (i.e., the K<sub>Ca</sub> or maxi-K channel). See page 27, in lines 24-28. The Christ declaration provides data regarding possession of two other K+ channels, Kv1.5 and SK3, which appear to cause less heightened contractility of penile smooth muscle. However, it appears that the calcium channel proteins, other than K<sub>ATP</sub> or maxi-K channel, were not described or embraced by the instant specification as the instant specification has stated only K<sub>ATP</sub> or maxi-K are present or physiologically relevant with respect to corporal smooth muscle. See page 4 of the Office action mailed on 7/29/02. This appears to suggest to the skilled artisan that other K+ channels may not be embraced by the invention and that Applicants were not in possession of the K+ channels at the time the invention was made.

Accordingly, the rejection is maintained for the reasons of record.

Claims 50-54 and 58-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods to the extent of nucleotide sequences encoding potassium channel proteins that are  $K_{ATP}$  or maxi-K, does not reasonably provide enablement for all other methods embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The previous rejection is maintained as it pertains to the newly added claims for the reasons of record advanced on pages 5-8 of the Office action mailed on 7/29/02.

Applicant's arguments filed on 5/20/03 have been fully considered but are not found persuasive. Applicants have provided the Christ declaration in support of the newly added claims.

The declaration under 37 CFR 1.132 filed 5/20/03 is insufficient to overcome the rejection of claims 50-54 and 58-59 based upon 35 U.S.C 112, 1<sup>st</sup> paragraph, as set forth in the last Office action because: The instant specification discusses that "despite the plethora of known K+ channel subtypes, experimental and clinical data in human corporal smooth muscle provide evidence for the presence and physiological relevance of only two: (1) the metabolically-gated K+ channel (i.e.,  $K_{ATP}$ ), and (2) the large-conductance, calcium-sensitive K+ channel (i.e., the  $K_{Ca}$  or maxi-K channel). See page 27, in lines 24-28. The Christ declaration provides data regarding possession of two other K+ channels, Kv1.5 and SK3, which appear to cause less heightened contractility of penile smooth muscle. However, it appears that the calcium channel proteins, other

than K<sub>ATP</sub> or maxi-K channel, were not considered enabled or embraced by the instant specification as the instant specification has stated only K<sub>ATP</sub> or maxi-K are present or physiologically relevant with respect to corporal smooth muscle. See page 7 of the Office action mailed on 7/29/02. As such it appears from the guidance provided by the instant specification that the other K<sup>+</sup> channels embraced by the claims were outside the scope of the enabled invention at the time the invention was made. It appears that the instant specification has not provided adequate guidance, teachings, or working examples that demonstrate or otherwise correlate to (how to) use the other K<sup>+</sup> channel proteins when practicing the methods as claimed.

Accordingly, the previous rejection is maintained for the reasons of record.

#### ***Allowable Subject Matter***

Claims 55-57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### **Conclusion**

**No claim is allowed.**

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

**PETER PARAS  
PATENT EXAMINER**

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